

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION**

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ISLET SCIENCES, INC., :
: :
Plaintiff, :
: :
v. :
: :
AVOLYNT, INC., BRIGHTHAVEN : 5:19-CV-145-D
VENTURES, LLC, WILLIAM WILKISON, :
and JAMES GREEN, :
: :
Defendants. :
: :
And :
: :
AVOLYNT, INC., BRIGHTHAVEN :
VENTURES, LLC, WILLIAM WILKISON, :
and JAMES GREEN, :
: :
Third-Party Plaintiffs, :
: :
v. :
: :
ISLET SCIENCES, INC., JOHN F. STEEL, :
IV., LARRY K. ELLINGSON, JAMES A. :
HARPER, RICHARD D. PILNIK, EUGENE :
M. MANNHEIMER, and GARY R. :
KEELING :
: :
Counterclaim/Third-Party Defendants. :
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**ISLET SCIENCES, INC. AND THIRD-PARTY DEFENDANTS'
MEMORANDUM IN SUPPORT OF THEIR MOTION TO COMPEL**

INTRODUCTION

This action arises from a commercial dispute between Plaintiff Islet Sciences, Inc. (“Islet”) and Defendant Brighthaven Ventures, LLC (“BHV”) pertaining to a revolutionary drug, the “Remo Technology,” used to treat metabolic diseases, such as diabetes and Non-Alcoholic SteatoHepatitis (“NASH”). BHV was on the verge of losing this pharmaceutical intellectual property due to its failure to commercialize and patent the technology, so it turned to Islet for assistance. Expecting to share the profits and losses, Islet entered into a joint venture with BHV that secured and expanded the Remo Technology. However, upon receiving Islet’s assistance, BHV abandoned the venture. Islet now seeks redress for BHV’s misconduct through claims of breach of a joint venture and fiduciary duties, unjust enrichment, fraud, and constructive trust.

Islet and third-party defendants Messrs. Steel, Ellingson, Harper, Pilnik, Mannheimer, and Keeling (collectively, “the Islet Parties”) issued discovery requests consisting of 30 Requests for Production (“RFP”) and 12 Interrogatories (“ROG”) to defendants BHV, Avolynt, Inc., William Wilkison, and James Green (collectively, “Defendants”). The RFP and ROG at issue in this Motion, RFPs 2, 4, 5, 7–12, 14 and 17–25 and ROGs 1–10 and 12 (collectively the “Requests”), seek materials regarding core aspects of liability and damages in this case.

Defendants responded to the Requests with boilerplate objections and by withholding materials based on a self-serving, unjustifiably narrow interpretation of Islet’s claims. This interpretation only came to light after the Islet Parties sought clarification of Defendants’ convoluted objections through a series of meet-and-confer letters [collated **Ex. 1**] and a telephone conference. This Court has already rejected Defendants’ previous attempts to thwart discovery by denying both Defendants’ motion to bifurcate liability and damages and their motion for a protective order seeking to bar the Islet Parties’ subpoenas to U.S. affiliates of

Defendants' international pharmaceutical partners. Defendants continue to resist discovery and withhold critical documents and information. The Islet Parties respectfully ask the Court to compel Defendants to produce the centrally relevant materials responsive to the Requests.

BACKGROUND

I. Islet Helped BHV Preserve and Develop the Remo Technology

In 2012, BHV was in bad shape. Out of money and time to preserve an essential technology license and to file critical worldwide patent filings, it needed a partner. Second Amended Complaint (ECF No. 53) ("SAC") ¶¶ 34, 41–43. Ultimately, BHV was connected with Islet, and the parties agreed to jointly develop and market the Remo Technology, with the proceeds split 80% to Islet and 20% to BHV. Term Sheet [Ex. 2]; SAC ¶¶ 58–75, 77–81. Soon after, Islet provided crucial assistance to BHV, whereby Islet incurred patent expenses, provided strategic guidance, and lent its goodwill to the benefit of the venture. *Id.* ¶¶ 84–96. As a result, BHV salvaged its business relationship with Kissei Pharmaceuticals, Ltd. ("Kissei"), which included a forbearance of significant costs, preserved a license to the Remogliflozin ("Remo") molecule and its salt carrier Remo Etabonate, and saved and secured global patent rights to a pharmaceutical formulation (collectively, Remo, Remo Etabonate, and patent rights, the "Remo Technology"). *Id.* ¶¶ 88–92. Unfortunately, BHV's loyalty was fickle. Mere days after receiving Islet's critical patent assistance, BHV started to unwind the deal. *Id.* ¶¶ 98–100.

BHV's ill-gotten gains have blossomed into deals across the globe. *Id.* ¶¶ 113–116. These partnerships include (1) Kissei, the Japanese licensor of the molecule underlying the Remo Technology; (2) Libbs Farmacêutica Ltda., a Brazilian partner of Defendants; and (3) Glenmark Pharmaceuticals Ltd. and Torrent Pharmaceuticals Ltd., Indian companies that obtained regulatory approval for, and now market, the Remo Technology in India. *See, e.g.*, Report of the Parties' Planning Meeting (ECF. No. 101) ("Planning Report") at 3-5. The present and future

value of these and other relationships is likely substantial. *See, e.g.*, SAC ¶ 115.

II. The Islet Parties’ Requests Seek Materials Central to their Claims and Defenses

Islet’s claims for breach of contract, breach of fiduciary duty, unjust enrichment, fraud, and constructive trust seek damages related to the Remo Technology assets. These assets include the Kissei relationship and associated license to Remo and Remo Etabonate, global patent rights to the biphasic formulation of the Remo drug, and the increased value of the Remo Technology because of its exploitation. *See, e.g.*, SAC ¶¶ 117-150 (Counts I-V). The need for the requested discovery has long been known to Defendants. *See*, Planning Report at 3-5. So have the theories of recovery. Initial Disclosures of the Islet Parties [Ex. 3], at 4 (“constructive trust, restitution, disgorgement, an accounting, or any other appropriate equitable or legal relief”).

On January 31, 2020, the Islet Parties sent 30 RFPs to each Defendant (each set, identical). *See* First Set of RFP [collated Ex. 4]. Then, on October 1, 2020, the Islet Parties sent 12 ROGs to Defendants. *See* First Set of ROG [Ex. 5]. Each discovery request was tailored to address issues central to this dispute.¹ The Requests relevant to this Motion can be roughly divided into six categories:

1. Benefits and uses of the Remo Technology, including clinical and regulatory activities (RFP 23, 24, 25; ROG 5, 6, 7, 10). These materials are critical to understand how the Remo Technology has, or will be, commercially developed. In turn, that development will show how Islet’s assistance to BHV increased the value of the Remo Technology. Specifically, these materials will describe the diseases that the Remo Technology can treat, and possible

¹ The Third-Party Defendants are entitled to this information because their defenses turn in part on issues central to this dispute. Specifically, as discussed in Islet’s Motion to Dismiss Counterclaims (ECF No. 93 at 6), Defendants’ claim for malicious prosecution requires special damages—in the context of this case, complete loss of property. *See Stanback v. Stanback*, 297 N.C. 181, 202, 254, S.E.2d 611, 625 (N.C. 1979). Accordingly, the value of the Remo Technology—an issue Defendants say is relevant only to damages—is in fact central to liability.

therapies that may be derived therefrom.

2. Defendants' efforts to advertise and promote the Remo Technology (RFP 2, 12). These documents implicate both liability and damages. For example, BHV's Remo advertising will evidence the parties' intention to jointly develop the drug. Concerning damages, these materials will show the drug's benefits and uses, which ultimately go to its valuation.

3. Procurement of Remo Technology patent rights, and their importance (RFP 4, 5). These documents will show that, during the joint venture, Islet and BHV exercised joint domain over the global rights to the biphasic patents. These documents will also show the nature and scope of Islet's assistance in securing and protecting one of the critical intellectual property assets at the heart of this dispute, and the extent of Defendants' unjust enrichment due to its value in the course of commercializing the Remo Technology.

4. Defendants' efforts to raise capital or obtain investors to support development and commercialization of the Remo Technology (RFP 7, 9, 10, 11, 12; ROG 12). The materials encompass, for example, Defendants' pitch materials to investors or bankers, which show BHV's precarious business position when it met Islet, which in turn evidences BHV's need for Islet's assistance and the value BHV enjoyed from that assistance. Additionally—central to damages determination—the materials will describe how the Remo Technology was, is, or will be, situated in the market for treatment of metabolic diseases, like diabetes and NASH.

5. Defendants' commercialization, business terms, and business dealings concerning the Remo Technology (RFP 8, 14, 17, 18; ROG 1, 2). These documents and information seek evidence of Remo Technology deal terms. Such materials will help quantify the Defendants' exploitation of the drug, and demonstrate the benefits Defendants received from Islet's critical assistance. These materials will also rebut Defendants' allegations of liability and

damages due to Third Party Defendants’ filing of the North Carolina state court litigation.

6. Remo Technology valuation, competition, and market (RFP 19, 20, 21, 22; ROG 3, 4, 8, 9). These materials relate to Islet’s damages because they inform the value of the Remo Technology from the perspective of both Defendants and the market. They are also needed for Islet’s unjust enrichment and fraud claims to show how BHV enticed Islet to become its business partner.

III. Defendants’ Boilerplate Responses and Refusal to Produce Responsive Materials

Defendants responded to the Requests with boilerplate objections. For example, in response to each RFP at issue (RFPs 2, 4, 5, 7–12, 14, and 17–25), Defendants used nearly identical language, that each request was “overbroad,” “not relevant,” and “not . . . proportional,” and—with respect to RFPs 2, 4, 7, 10–12, 14, and 17–25—claiming that responding “would subject Defendant[s] to undue burden.” *See* Responses to RFP [collated **Ex. 6**]. Moreover, while some of the responses stated that “responsive, non-privileged documents” would be produced (RFPs 5, 7, 8, 10–12, and 14), other responses, contrary to Rule 26, made no statement as to whether Defendants intended to withhold materials (RFPs 2, 4, and 17–25).

Initially, the Islet Parties simply requested an explanation of the boilerplate objections (*i.e.*, “not relevant,” not “proportional to the needs of the case,” and/or “confidential and proprietary”), May 20, 2020 Letter, Ex. 1, at 3 (Boilerplate Objections), and the meaning of Defendants’ silence as to the production of certain documents, *Id.* (Failure to Specify). However, through this meet-and-confer process, the Islet Parties learned that Defendants’ apparent agreement to produce “responsive” documents (RFPs 5, 7, 8, 10–12, and 14) was misleading. Defendants took the position, for all the Requests at issue in this Motion, that because “Islet’s claims . . . are entirely focused on its assertion of the existence of a . . . joint venture” which was limited in “time, territory, and “scope,” no documents would be produced “outside the scope” of

Defendants' self-serving interpretation of Islet's claims. Jun. 26, 2020 Letter, Ex. 1, at 3–4.

Islet responded by explaining that this case is not limited to the Term Sheet, as Islet also pleaded breach of fiduciary duty, unjust enrichment, and fraud, which entitles Islet to discovery for *each* claim. Sept. 23, 2020 Letter, Ex. 1, at 1-2. Moreover, with respect to the joint venture, Islet pointed out that BHV's "conduct demonstrate[d] that the relevant territories and treatment applications are broader than asserted by Defendants." *Id.*, at 2. Yet, despite this explanation, Defendants still refused to produce the requested materials. Sept. 30, 2020 Letter, Ex. 1, at 1–2.

As to ROG 1–10 and 12, Defendants provided boilerplate proportionality objections that simply regurgitated the Fed. R. Civ. P. 26(b)(1) factors.² *See* Responses to ROG [Ex. 7]. They also withheld information based on the same "outside the scope" objection as with the RFPs, except for providing partial and deficient responses to ROGs 10³ and 12⁴. *Id.* at 2–14.

This motion seeks to correct Defendants' wrongful withholding of materials.

ARGUMENT

Defendants have no proper basis for their refusal to provide information and documents and must respond in full. A litigant may obtain discovery "relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). This standard is given "a broad and liberal treatment to effect their purpose of adequately informing the litigants in civil trials." *Infernal Techn., LLC v. Epic Games, Inc.*, 335 F.R.D. 94, 96 (E.D.N.C. 2020)

² Defendants responded to the ROGs after the meet and confer process. Thus, their objections incorporate the relevancy issue from the discovery letters. *See* Ex. 7, at 2-14.

³ When asked to identify clinical trials Defendants have or plan to conduct, Defendants identified a single U.S. trial. This is incomplete and improper. The Islet Parties know of at least a trial in India, which lead to market approval. *See* Avolynt Aug. 22, 2016 Press Release [Ex. 8].

⁴ When asked to identify entities with a financial interest in the Remo Technology, including all payments to those entities, Defendants responded that BHV paid Kissei, but provided none of the requested payment information. Ex. 4, at 13-14. Additionally, the Islet Parties know of at least one other entity, Libbs, with a financial interest in the Remo Technology. *See* Islet and BHV Oct. 6, 2014 Press Release [Ex. 9] (noting Libbs invested \$1.5 million in BHV).

(citations omitted). If a party fails to produce the requested materials, the party seeking discovery may “move for an order compelling . . . an answer [or] production” and seek sanctions. Fed. R. Civ. P. 37(a)(3)(B), (5). Faced with a motion to compel, the resisting party has “the burden of showing why [the discovery requests] should not be granted.” *Brey Corp. v. LQMgmt., L.L.C.*, No. 11-cv-00718-AW, 2012 WL 3127023, at *4 (D. Md. 26 Jul. 2012) (citations omitted). Here, Defendants’ discovery responses are significantly incomplete because: (1) Defendants’ withholding of materials central to the dispute is based on a unilateral mischaracterization of Islet’s claims and defenses; (2) Defendants have provided no support whatsoever for their conclusory assertion that the Requests are not proportional to the needs of the case; and (3) Defendants’ remaining objections are improper boilerplate.

I. The Requested Discovery is Central to This Case.

Defendants refuse to produce responsive materials on relevance grounds. This objection is improper because it is the Islet Parties’ pleadings that determine the scope of their claims and defenses. Defendants “cannot unilaterally decide to limit discovery requests based on what . . . [they believe] is relevant.” *Hirsch v. USHealth Advisors, LLC*, NO. 4:18-CV-245-P, 2020 WL 1271588, at *7, 10 (W.D. Tex. Feb. 14, 2020); *see also Spendlove v. RapidCourt, LLC*, No. 3:18-cv-856, 2019 WL 7143664, at *5 (W.D. Va. Dec. 23, 2019) (noting that “it is improper for [the defendant] to unilaterally withhold information or documents that are responsive to a discovery request by stating that ‘all relevant, non-privileged’ information will be produced.”). Moreover, “[t]he court should and ordinarily does interpret ‘relevant’ very broadly to mean matter that is relevant to anything that is or may become an issue in the litigation.” *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 n. 12 (1978).

Contrary to Defendants’ position, the Requests are not only relevant, they seek materials central to Islet’s claims and defenses. Fed. R. Civ. P. 26 (b)(1). *First*, with respect to liability, the

Requests seek materials relevant to the formation and terms of the joint venture, as well as Islet’s four additional causes of action: breach of fiduciary duty, unjust enrichment, fraud, and constructive trust. The general timeframe of such discovery ends in October 2013 (Ex. 2, ¶ 3 (Instructions))—the time by which the transaction in dispute ended. *See, e.g.*, Ex. 3, RFP 7 (materials “concerning BHV’s need or desire for financial support, expertise, or a business relationship, to develop or commercialize the Remo Technology.”), RFP 8 (materials “concerning Islet’s role in developing and commercializing, or assisting [Defendants] in developing and commercializing the Remo Technology.”). **Second**, with respect to damages, the Requests seek materials that identify and value the Remo assets that resulted from Defendants’ association with Islet, including both revenues and profits that Defendants have already enjoyed, and the inherent value of the Remo Technology, as measured by its potential for future commercialization. *See Restatement (Third) of Restitution and Unjust Enrichment § 51 (2011), 4-5(a)* (the “enrichment of a conscious wrongdoer . . . is the net profit attributable to the underlying wrong,” which may include “*any form of use value, proceeds, or consequential gains.*”) (emphasis added). Thus, in contrast to liability, the timeframe for damages discovery extends beyond October 2013, because Defendants continue to realize benefits from Islet’s contribution through present day. For example, Islet’s assistance allowed Defendants to form a business relationship with Glenmark, *see Avolynt, Products [Ex. 10]*, and to pursue Remo Technology for the treatment of NASH. *See Ex. 9.* Without Islet’s support, BHV would never have had the opportunity to pursue these and other ventures. Such ventures are therefore centrally relevant to the determination of damages. *See, e.g.*, Ex. 3, RFP 21 (requesting “[d]ocuments and communications sufficient to show, actual and projected, market size for the Remo Technology.”); Ex. 4, ROG 5 (asking Defendants to “[i]dentify each country where the

Pharmaceutical Technology has been approved for marketing . . . and the treatment uses or indications approved within each country.”).

II. The Requested Discovery Is Proportional to the Needs of this Case.

The proportionality of a discovery request is assessed by “considering the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.” Fed. R. Civ. P. 26(b)(1). These factors uniformly weigh in favor of the Islet Parties. As noted above, these documents and information are central to liability and damages. Moreover, the best-in-class Remo Technology is or has the potential to be worth billions, given that approved competing drugs collectively resulted in over \$2.5 billion in revenue in 2017. *See, e.g.*, SAC ¶ 115; *see also U.S. ex rel. Guardiola v. Renown Health*, No. 3:12-CV-00295-LRH, 2015 WL 5056726, at *10 (D. Nev. Aug. 25, 2015) (discovery costs of \$136,000 not unduly burdensome where multi-million dollar claims are at issue). As to access, Defendants and their third-party collaborators are the best, and possibly only, source to provide this information.

Defendants’ objections claim burden. Ex. 3, RFP 2, 4, 7, 10–12, 14, and 17–25. However, these allegations should be rejected as “claims of undue burden should be supported by a statement (generally an affidavit) with specific information demonstrating how the request is overly burdensome.” *Bank of Mongolia v. M & P Glob. Fin. Serv., Inc.*, 258 F.R.D. 514, 519 (S.D. Fla. 2009). In their 16 objections of undue burden, not *once* do they provide *any* explanation of an alleged burden. *See Weller v. Am. Home Assur. Co.*, No. 3:05-cv-90, 2007 WL 1097883, at *5 (N.D.W.Va. April 10, 2007) (finding no undue burden where the Defendant “failed to produce specific information regarding the amount of time” or “monetary cost of

compliance.”). Had they done so, the Islet Parties could have adjusted the Requests to address any avoidable burden or lack of proportionality. Defendants chose not to.

III. Defendants’ Boilerplate Objections Are Improper and Should Be Waived

Defendants’ boilerplate objections to relevancy, overbreadth, proportionality, and undue burden for each RFP at issue (2, 4, 5, 7–12, 14, and 17–25) and to proportionality for each ROG at issue (1–10 and 12) are improper. *Silicon Knights, Inc. v. Epic Games, Inc.*, 917 F.Supp.2d 503, 533 (E.D.N.C. 2012) (Dever III, J.) (granting a motion to compel after noting that plaintiff’s responses “comprise[d] nothing but a laundry list of boilerplate objections” that “fail to articulate any specific objection to any particular interrogatory or request for production.”). Defendants’ objections are so deficient that the ROG responses failed to raise any privilege or work product protections. The appropriate remedy for these deficient RFP and ROG responses is waiver of all boilerplate objections, including Defendants’ relevancy, overbreadth, proportionality, and undue burden objections. *Dean v. Jones*, No. 5:16-CT-03109-FL, 2018 WL 8967673, at *3 (E.D.N.C. Feb. 23, 2018) (“Defendant Jones’s boilerplate objections . . . are waived”); *Avent v. State Farm Fire & Cas. Co.*, No. 5:16-CV-278-BO, 2017 WL 2671078, at *2 (E.D.N.C. June 20, 2017) (“Objections not made timely are waived, subject to the court excusing the untimeliness for good cause.”). Given Defendants’ unreasonable resistance to these Requests, the Islet Parties also request this Court award reasonable fees and costs related to this Motion. *See Garner v. Vradelis*, No. 4:09-CV-21-D, 2009 WL 10688047, at *3 (E.D.N.C. Oct. 13, 2009) (noting that award of expenses “is appropriate where the moving party has acted in good faith . . . and the non-moving party has failed to comply with its obligations under the Federal Rules of Civil Procedure.”).

CONCLUSION

For the foregoing reasons, the Court should compel Defendants to respond in full to RFP 2, 4–5, 7–12, 14 and 17–25 and ROG 1–10 and 12, no later than 30 days after the Court’s ruling.

Dated: December 22, 2020

Respectfully submitted,

/Robert C. Van Arnam/

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of December, 2020, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system.

By: */Robert C. Van Arnam/*
Robert C. Van Arnam